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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,443	06/29/2001	Michael Gmachl	0652.2310001/EKS/SEZ	6378

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EXAMINER	
TUNGATURTHI, PARITHOSH K	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 01/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/893,443	GMACHL ET AL.	
	Examiner	Art Unit	
	Parithosh K. Tungaturthi	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28,30-46,48-66 and 68-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,33-46,49, 50, 53-66, and 71-83* is/are rejected.

7)☒ Claim(s) *30-32,48,51,52 and 68-70* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/03/05 has been entered.

2. The amendment filed 11/03/05 is acknowledged and entered into the record.

3. Accordingly, claims 1-27, 29, 47 and 67 are canceled without prejudice or disclaimer.

4. Claims 28, 30-46, 48-66, and 68-83 are pending and examined on the merits.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections

6. The rejection of claims 28, 33-46, 49-50, 53-66 and 71-83 under 35 USC 112, 1st paragraph as lacking written description is maintained for the reasons of record. Applicant argues that one of skill in the art would be able to recognize the features of the E1 and E2 enzymes broadly claimed.

Applicant points to several passages in the specification for support of the generic claim of E1 and E2 enzymes. Additionally, applicant contends that information of other E1 and E2 enzymes can be found conventionally in the art. Applicant also contends that the E1 and E2 enzymes in the present claims are not being claimed per se, but the use of the enzymes in a method of screening for inhibitors.

Applicant argues, "In Amgen, the claims at issue were directed to methods for producing a glycosylated erythropoietin polypeptide. See Amgen at 1390. The claimed methods included, inter alia, the step of "growing, under suitable nutrient conditions, vertebrate cells comprising amplified DNA encoding the mature erythropoietin amino acid sequence of FIG. 6.:' See id. Also at issue were dependent claims that specified that the cells were mammalian cells. See Amgen at 1391. Just as E1 and E2 in the present claims are not being claimed per se, the claims at issue in Amgen were not directed to vertebrate cells or mammalian cells per se. Rather, the cells were simply an element used in the practice of the claimed methods.....And thus, even though Amgen's patents described only "two species of vertebrate or mammalian cells," the Federal Circuit found such disclosure to provide adequate written description support for the entire genus of vertebrate or mammalian cells used to produce EPO according to the claimed methods." (Please see pages 13-15 of the response).

It is also noted that on pages 15-17, the applicant argues that the terms "ubiquitin activating enzyme (E1)" and "ubiquitin conjugating enzyme (E2)" like the terms "vertebrate" and "mammalian", co not refer to new or unknown biological materials that

ordinary skilled artisans would easily miscomprehend. The applicant further points that the recitation of E1 and E2 should satisfy the written description, because, the functional pathway of the enzymes E1 and E2 was common knowledge in the art at the time of the effective filing date of the present application.

The applicant also points Example 18 of the USPTO's "Synopsis of Application of Written Description Guidelines", wherein it illustrates an analysis of the written description provided for a process claim where the novelty is in the method steps (please see pages 18-20 of the response).

The applicant in conclusion argues (please see pages 20-21 of the response) "Example 18 of the USPTO'S Guidelines emphasizes the need to consider the level of skill and knowledge in the relevant art in assessing adequacy of written description. As discussed above, the level of skill and knowledge in the art of E1 and E2 enzymes was extremely high, especially considering that multiple members of these enzyme classes had been identified and characterized at the time of the effective filing date of the present application. (The Examiner has not presented any evidence to suggest that the level of skill and knowledge in the art of E1 and E1 enzymes was not high). The high level of skill and knowledge in the art reinforces the conclusion that the written description requirement is fully satisfied for the currently presented claims. The Examiner's application of the written description requirement in the present case appears to assume that E1 and E2 are new compounds that are being directly claimed', however, this is not the case. Neither E1 nor E2 are (or were) new compounds and they are not being directly claimed. To the contrary E1 and E2 are enzymes having well

defined activities, and numerous species of E1 and E2 enzymes had been identified and studied for several years prior to the effective filing date of the present application. The claims simply include the use of these two well-characterized classes of enzymes in the context of a novel method. The requirement for "structural characteristics that are shared by members of the genus of E1 and E2 family of enzymes" is legally improper since persons of ordinary skill in the art would clearly appreciate and visualize the full range of enzymes represented by E1 and E2 without any need for disclosure of common structural characteristics. In view of the current state of the law on adequacy of written description (e.g., Amgen) and the USPTO'S own guidelines on this topic, it must be concluded that the written description requirement of 112, first paragraph, is fully satisfied for the currently presented claims. Applicants respectfully request that this rejection be reconsidered and withdrawn."

Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The instant claims do not provide sufficient structural and functional characteristics coupled with a known or disclosed correlation between function and structure. While it may be true that E1 and E2 enzymes may be well known and their activities definitively established as early as 1982, the disclosure fails to describe the common attributes or characteristics that identify members of the genus of E1 and E2 enzyme family. Although it is readily accepted that E1 and E2 are involved in the

pathway for ubiquitination, the existence of different variants or isoforms disclosed in the specification would lead to a difference in structure and possible function.

Further, neither "Hatfield and Vierstra" nor "Jensen et al" teach that all known E1 and E2 enzymes share similar molecular pathway. Hatfield and Vierstra characterized the importance of the cysteine residues in UBA1 and Jensen identified a family of closely related human ubiquiting conjugating enzymes. In contrary, Jensen et al points out that the functions for the multitude of E2 enzymes that exist, include roles in DNA repair, cell cycle progression, organelle biogenesis, secretion, and stress response (please see introduction in particular). Jensen et al points out that there atleast two examples where two ubiquitin conjugating enzymes function in concert to transfer ubiquitin to a specific target protein and that "two closely related *S. cerevisiae* E2s, ScUBC4 and ScUBC5, play important roles in the turnover of normal and abnormal proteins". This statement confirms that not all E2 or E1 enzymes have similar functional properties, because the depending on the isoforms and the interaction between these different isoforms, the function of the ubiquitin conjugating enzyme (or for that matter ubiquitin activating enzyme) can vary.

The comparison of the instant application with the *Amgen Inc. v. Hoechst Marion Roussel Inc.,* and with "Example 18 of the USPTO'S Guidelines" is noted, but not found persuasive for a satisfactory written description in the instant claims as they are presented. The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112 1st paragraph "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of

species', then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111 , Friday January 5, 2001 , see especially page 1 106 column 3).

In the absence of structural characteristics that are shared by members of the genus of E1 and E2 family of enzymes, the skilled artisan would conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. See Universitv of California v. Eli Lillv and Co. 119 F.3d 1559, 43 USPQZd 1398 (Fed. Cir. 1997). The support indicated by the applicant in the specification that would provide the skilled artisan with some guidance or indication of possession of the claimed E1 and E2 enzymes is general guidance. Instead, what is required in specific disclosure by structure, function, or a correlation between structure and function.

And finally, since E1 and E2 enzymes are claimed and exist as an important component in the claimed method, the claims require an adequate written description of the "El and E2" enzymes employed in the methods. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112 1st paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001. "Adequate written description requires a precise

definition, such as by structure, formula, chemical name or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." Id. at 1566, 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). Also see Enzo-Biochem v. Gen-probe 01-1230 (CAFC 2002).

Conclusion

7. No claims are allowed

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is 571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Parithosh K. Tungaturthi, Ph.D.
Ph: (571) 272-8789

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER